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(57) Abstract

A protective article, e.g. a surgeon's glove, comprises inner and outer layers of transparent or translucent polymeric material. Between the layers is sandwiched a solid particulate water-soluble dye. On rupture of the glove, liquid enters the cavity between the layers and dissolves the dye. This causes a colour change which warns the user that the glove has been ruptured.

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PROTECTIVE ARTICLES

The present invention is concerned with protective articles, of the kind which are designed to indicate if a breach of their protective integrity has occurred. One example of a protective article according to the invention is a surgeon's glove.

It is estimated that some 25% of surgeons gloves are perforated by the end of an operation. In order to reduce the chance and severity of such perforations surgeons typically wear two pairs of gloves. The current problems with Hepatitis and AIDS have made surgeons and others involved in treating such patients even more aware than before of the potential risk of being contaminated by patients blood or other body fluids.

Clinica, No. 337, p24, 1989 describes a double layered glove with a dark coloured inner layer and a lighter coloured outer layer, the two being held in close contact by a vacuum such that the colour of the darker inner layer is predominant. If perforated the layers separate and the colour of the outer layer becomes more prominent. An alternative colour change system is suggested of providing a water or oxygen sensitive chemical indicator between the layers but no details are given. The gloves have not achieved commercial success.

There is a need for protective articles, in particular surgeon's gloves, and gloves for other medical purposes including examination, which will warn the user immediately by highly visible colour change that perforation of the protective article has occurred and that he should immediately consider replacement.

This inv ntion provides a protective article

comprising an inner layer and on overlying outer layer, the outer layer being translucent or transparent and both layers being of polymeric material and impermeable to fluid, the two layers being sealed together so as to define between them a closed cavity within which is dispersed a powdered soluble dye which, on perforation of either layer and entry of fluid into the cavity, dissolves in the fluid in the cavity to exhibit a colour change visible through the outer layer.

The protective article comprises an inner layer and an overlying outer layer. Both layers are impermeable to the fluid, generally aqueous fluid such as water or body fluids with which the article is likely to come into contact. Both layers are of the same or different polymeric material. Either or both layers may be rigid, but more usually both layers are flexible sheets of rubber or a plastics material. Particularly for surgeon's gloves, latex rubber is the preferred material. The outer layer needs to be translucent or transparent, to the extent that the colour change, resulting from perforation of either layer, is visible through it.

The two layers are sealed together, so as to define a closed cavity between them. It is generally convenient for one layer to be sealed to the other layer along a continuous line extending round its periphery. That continuous line then forms a ring within which is defined a closed cavity between the two layers.

Within this cavity is dispersed a powdered soluble dye. The particles of dye are of a sufficiently small size and dispersed sufficiently widely that they are substantially invisible through the outer layer and do not substantially colour the article. The particle size of the powdered dye may be as small as conveniently possible. The dye may be

present in admixture with a colourless extender. The dye needs to be soluble in fluid, for example aqueous fluid such as body fluids, with which the article is expected to come in contact.

If either layer is perforated, then it becomes possible for fluid to enter the cavity between them. The fluid may tend to spread by capillary action within the cavity, because the outer layer overlies the inner layer. The dye dissolves in the fluid, and the colour of the dye is imparted to the fluid and becomes visible through at least the outer layer of the article.

Preferred dyes are highly water soluble and of dark colour, i.e. having a high colour density, such as black or blue, since this produces a more dramatic colour change against the normal colour of rubber or plastic sheets. However, any water soluble dye which can be provided in powder form can be used. The colour should be chosen to give a large change in colour tone from that of the colour of the outer layer (or seen through the outer layer) of the article itself. Preferred dyes include diazol brilliant blue GL GMS50 and diazol fast black JRA 2UAD, both supplied by ICI.

The powdered dye may be dispersed throughout the cavity or in specific regions within the cavity. The density of the particle dispersion, and the size of the dye particles, should be chosen such that there is a marked and easily visible colour change when fluid enters the cavity.

Preferably the particle dispersion is present at a density of 0.1 - 10.0 g/m^2, particularly 0.2 - 2.0 g/m^2. At densities outside this range the colour change, on perforation of either layer and solution of the dye in incoming fluid, may be too slight to be easily observed.

Preferably the dispersed particles have an average size in the range of 1 - 100 μm. Larger particles may be satisfactory if they can be uniformly dispersed in the cavity and if they dissolve sufficiently rapidly in incoming fluid to generate the desired colour change.

Bags, for example laboratory sample bags constitute one example of protective articles according to this invention. Some laboratory practices require the double bagging of many substances. There is a need for a purpose-made bag which would rapidly indicate any perforation or leakage. Double walled bags are formed with one layer inside the other, the two layers being sealed together around the neck of the bag, and a powdered soluble dye being dispersed in the resulting cavity between the two layers.

Another example of protective articles according to the invention are condoms, which may be constructed along the same lines as gloves (see below).

Although the examples specifically mentioned herein may be regarded as containers, the invention is not limited to articles which are containers. Tamper-proof seals or other flat sheet formats are readily made according to the invention.

A preferred example of protective articles according to the invention is, as mentioned above, gloves particularly examination gloves and surgeon's gloves. Surgeon's gloves are currently made with one or two layers of PVC film or more usually latex rubber, of which at least the outer layer is translucent or transparent. Total film thickness is usually of the order of 0.05 mm to 0.5 mm. Gloves according to this invention may conveniently be formed by hermetically sealing the inner layer and the outer layer around the wrist, with the powdered dye contained in the cavity so formed. Alternatively, the glove may be constructed

such that a number of cavities are formed between the two layers, all or only some of which contain the dye. As a further alternative, the glove may be constructed such that the double layer is applied only to more vulnerable areas, for example the thumb and forefinger, the remainder of the glove being of single layer construction.

Example 1

Two identical surgeon's gloves were produced by a standard natural rubber latex dipping process. The thickness of each glove was 0.12 to 0.15 mm. One glove was placed on a former identical to the one on which it had been made, taking care to prevent air entrapment. Any powder on the outside surface was removed by washing with isopropanol. The dye was applied as a fine powder in a 1:1 mixture with an inert colourless material such as corn starch or sodium chloride. A latex adhesive was applied to a ring about 2 cm around the cuff and the four crotch regions. This was dried for a few minutes at 70°C. The second glove was pulled on to the former-supported glove taking care to exclude visible air bubbles. The two gloves were sealed by applying hand pressure to the adhesive treated regions. The complete glove was stripped from the former.

Powdered materials adhere readily to latex rubber surfaces. In surgeon's gloves according to this invention, it is advantageous to have quite a lot of powdered material between the two layers, to provide a measure of lubrication. If the dye were used as the sole powdered material for this purpose, the glove would be too dark in its initial state for any very obvious colour change to be visible after perforation and ingress of fluid. It is therefore convenient to mix the dye with an extender. As received, the dyes

were coarsely particulate materials. They were therefore mixed with corn starch and the mixture ground to a finer particle size. The weight ratio of dye:corn starch used was 1:1, but this can readily be varied so as to provide a desired colour intensity of the glove, both before and after perforation. If the powdered mixture is simply poured over the inner latex rubber layer on the former, enough sticks to the rubber surface to provide the desired lubricating and colour-change effects.

It may be advantageous to assemble the glove finger tips down, so that any loose powder tracks to the finger tips which are the most likely site for perforation.

A pair of gloves was made as described above using the diazol brilliant blue GL GMS50 dye. A fairly high density of dye was used, and the gloves looked slightly darker than ordinary surgeon's gloves before they became covered in body fluids. Once covered in body fluids, they were virtually indistinguishable from ordinary gloves. As soon as a perforation was created at a finger tip, a good colour change occurred which was easily visible even with the gloves still covered in body fluids.

Another pair of gloves was made using diazol fast black JRA 2UAD dye. The dye was used at a lower density such that even in the air the gloves were indistinguishable from unpigmented double gloves. When immersed in body fluids and perforated, a colour change occurred which was, however, less obviously noticeable than was the case with the earlier pair.

Example 2

Process for making the IND-X Glove

Materials Required

Beadless surgical glove with palm thickness 0.14-0.15 mm approx. (inner layer).

Beadless surgical gloves with palm thickness 0.17 - 0.18 mm approx. (outer layer).

Diazol brilliant blue dye.

Dry alcohol e.g. dried industrial methylated spirit.

A latex contact adhesive.

Cotton wool sticks or the like.

Equipment Required

Former identical to one used to make the gloves above.

High speed grinding mill e.g. Silverson.

Oven at 70°C.

Brushes.

Stirred vessel.

Preliminaries

1. Both gloves must be of same size and must be well leached, fully dried and coated with bioabsorbable corn starch or other surface coating.

2. The dye is suspended in the dry alcohol at a concentration of about 5% using a Silverson stirrer. This has the effect of reducing the particle size of the dye as well as dispersing it. The particles in the dispersion range from 1 - 120 µm in size, with the majority in the range 10 - 20 µm.

Procedure

1) Pull the thin glove onto the former until all finger tips are in contact with the former and no creases remain in glove.

2) Support former over a collecting vessel with fingers pointing downwards.

3) Apply suspension dye, which is being continuously stirred, to the glove with a brush. Allow the excess to drain downwards. This has the effect of removing some of the powder coating as well.

4) Dry in air to leave a coating of dye all over the glove except for about a 5 cm ring around cuff. A typical glove has about 0.03 g of particulate dye, corresponding to a density of about 0.7 g/m^2.

5) Using cotton wool sticks soaked in alcohol, remove all powder (dye and corn starch) for finger tips, crotch between fingers and 5 cm band near cuff.

6) Apply the latex adhesive to the areas mentioned in 5).

7) Dry adhesive completely at 70°C (about 5-10 mins).

8) Pull the second glove onto the first with cuff folded over.

9) Press down finger tips and crotches to complete bonding and exclude as much air as possible from between the layers.

10) Roll down the cuff of the outer glove over the inner and press to complete bonding.

11) Strip the completed IND-X glove from the former and evert the glove.

37 pairs of the gloves so made have been subjected to clinical trials by six surgeons in various hospitals. Reaction has been very favourable. The gloves are reported as comfortable, sensitive and robust in use. When perforation of either layer does take place, the resulting blue discolouration is easily seen, even when little body fluids are present.

CLAIMS

1. A protective article comprising an inner layer and on overlying outer layer, the outer layer being translucent or transparent and both layers being of polymeric material and impermeable to fluid, the two layers being sealed together so as to define between them a closed cavity within which is dispersed a powdered soluble dye which, on perforation of either layer and entry of fluid into the cavity, dissolves in the fluid in the cavity to exhibit a colour change visible through the outer layer.

2. Protective article as claimed in claim 1, wherein both layers are flexible films of rubber or plastics material.

3. Protective article as claimed in claim 1 or claim 2, wherein both layers are of latex rubber.

4. Protective article as claimed in any one of claims 1 to 3, wherein the dye is soluble in water and body fluids to exhibit the desired colour change.

5. Protective article as claimed in any one of claims 1 to 4, wherein the powdered dye is present in admixture with a colourless carrier.

6. Protective article as claimed in any one of claims 1 to 5, wherein the article is a glove.

7. Protective article as claimed in claim 6, wherein the glove is a surgeon's glove.

8. Protective article as claimed in any one of claims 1 to 5, wherein the article is a bag.

9. Protective article as claimed in any one of claims 1 to 5, wherein the article is a condom.

10. Protective article as claimed in any one of claims 1 to 9, which is supplied in sterile form.

INTERNATIONAL SEARCH REPORT

Inten nal Application No
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A. CLASSIFICATION OF SUBJECT MATTER
IPC 5 A61B19/04 A61F6/04

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 5 A61B A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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Y	see claims 1,5	8
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	see page 12, paragraph 1	
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Y	DATABASE WPI Section Ch, Week 9135, Derwent Publications Ltd., London, GB; Class B07, AN 91-256049 & JP,A,3 165 770 (NIPPON MED SUPPLY K) 17 July 1991 see abstract	8

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
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International application No.
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INTERNATIONAL SEARCH REPORT

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